



**Europäisches
Patentamt**

**Eur pean
Patent Office**

**Office européen
des brevets**

Bescheinigung

Certificate

Attestation

Die angehefteten Unterla-
gen stimmen mit der
ursprünglich eingereichten
Fassung der auf dem näch-
sten Blatt bezeichneten
europäischen Patentanmel-
dung überein.

The attached documents
are exact copies of the
European patent application
described on the following
page, as originally filed.

Les documents fixés à
cette attestation sont
conformes à la version
initialement déposée de
la demande de brevet
européen spécifiée à la
page suivante.

Patentanmeldung Nr. Patent application No. Demande de brevet n°

02388059.4

Der Präsident des Europäischen Patentamts:
Im Auftrag

For the President of the European Patent Office

Le Président de l'Office européen des brevets
p.o.

R C van Dijk



Anmeldung Nr.:
Application no.: 02388059.4
Demande no.:

Anmeldetag:
Date of filing: 09.09.02
Date de dépôt:

Anmelder/Applicant(s)/Demandeur(s):

NOVO NORDISK A/S
Novo Allé
2880 Bagsvaerd
DANEMARK

Bezeichnung der Erfindung/Title of the invention/Titre de l'invention:
(Falls die Bezeichnung der Erfindung nicht angegeben ist, siehe Beschreibung.
If no title is shown please refer to the description.
Si aucun titre n'est indiqué se référer à la description.)

Flow restrictor with safety feature

In Anspruch genommene Priorität(en) / Priority(ies) claimed / Priorité(s)
revendiquée(s)
Staat/Tag/Aktenzeichen/State/Date/File no./Pays/Date/Numéro de dépôt:

Internationale Patentklassifikation/International Patent Classification/
Classification internationale des brevets:

A61M5/142

Am Anmeldetag benannte Vertragsstaaten/Contracting states designated at date of
filing/Etats contractants désignées lors du dépôt:

AT BE BG CH CY CZ DE DK EE ES FI FR GB GR IE IT LI LU MC NL PT SE SK TR

FLOW RESTRICTOR WITH SAFETY FEATURE

FIELD OF THE INVENTION

5 The present invention relates to a flow restrictor suitable for the controlled transfer of fluid from a first compartment to a second compartment. More specifically, the invention relates to a safety arrangement reducing the risks associated with diminished flow resistance through the flow restrictor. Such flow restrictors are suitable for the application in fluid delivery devices of the bleeding hole type, such devices being suitable in particular for the in situ administration of a therapeutic drug preparation over a prolonged period of time, however, such devices may also be used in areas such as biochemistry, microbiology and chemical analysis.

BACKGROUND OF THE INVENTION

15 In the disclosure of the present invention reference is mostly made to the treatment of diabetes by injection or infusion of insulin, however, this is only a preferred use of the present invention.

20 Diabetes mellitus is the common name for at least 2 different diseases, one characterised by immune system mediated specific pancreatic beta cell destruction (insulin dependent diabetes mellitus (IDDM) or type 1 diabetes), and another characterised by decreased insulin sensitivity (insulin resistance) and/or a functional defect in beta cell function (non-insulin dependent diabetes mellitus (NIDDM) or type 2 diabetes).

25 The principal treatment of type 1 diabetes is straight forward substitution of the missing insulin secretion, whereas treatment of type 2 is more complicated. More specifically, in early stages of type 2 diabetes treatment a number of different types of drugs can be used, e.g. drugs which increase insulin sensitivity (ciglitazones), decrease hepatic glucose output (e.g. metformin), or reduce glucose uptake from the gut (alfa glucosidase inhibitors), as well as
30 drugs which stimulate beta cell activity (e.g. sulfonylurea/meglitinides). However, the above-described deterioration is reflected in the fact that beta cell stimulators will eventually fail to stimulate the cell, and the patient has to be treated with insulin, either as mono therapy, or in combination with oral medication in order to improve glucose control.

35

Currently, there are two principal modes of daily insulin therapy, the first mode including syringes and insulin injection pens. These devices are simple to use and are relatively low in cost, but they require a needle stick at each injection, typically 3-4 times or more per day. The second mode is infusion pump therapy, which entails the purchase of a relatively expensive pump, for which reason the initial cost of the pump is a barrier to this type of therapy. Although more complex than syringes and pens, the pump offer the advantages of continuous infusion of insulin, precision in dosing and optionally programmable delivery profiles and user actuated bolus infusions in connections with meals.

Basically the infusion pump comprises means for allowing the contained insulin to be transferred to the body of the patient. These means may take any desirable form providing the desired function, but presently pump arrangements comprising a conveying arrangement connected to the reservoir (i.e. an outlet to be associated with needle infusion means) and including a pressure or suction generating device for feeding the liquid contained in the reservoir by pressure or suction application from the reservoir to the body are preferred for transferring the insulin contained in the reservoir to the patient. In this respect a number of different principles may be utilized, e.g. osmotic pumps as known from for example US patents 4,340,048 and 4,552,561, piston pumps as known from for example US patent 5,858,001, membrane pumps as known from for example US patent 6,280,148, flow restrictor pumps (also known as bleeding hole pumps) as known from for example US patents 2,605,765 and 5,957,895, and gas generating pumps as known from for example US patent 5,527,288, which all in the last decades have been proposed for use in durable (refillable) and/or disposable (prefilled) drug infusion systems. As some of these principles may not be considered to be pumps in the traditional sense, it may be more appropriate to generally describe these devices as delivery means for fluid, however, in the following description the traditional term pump will be used.

Of the above pump principles, the present invention specifically addresses the bleeding hole pump. Basically, this principle provides a means for establishing a flow of a fluid at a desired rate by applying a force to a liquid to thereby force the liquid through a flow restrictor, the flow rate being determined by the applied force, the flow resistance in the flow restrictor and the viscosity of the fluid. For the purpose of expelling a drug from a reservoir, two variants of this principle have been described.

In a first variant the drug to be infused is contained in a reservoir in fluid communication with an outlet through a flow restrictor. When the drug is pressurized by an actuating (driving) force it is forced through the flow restrictor at a rate determined by the applied force, the flow resistance in the flow restrictor and the viscosity of the drug, see for example US patent
5 5,957,895 which discloses an infusion device in which the driving force is provided by a drug reservoir formed between two Belleville springs, the flow restrictor being provided by the through-going channel of a capillary tube, or WO 02/15965 disclosing an infusion device in which the flow restrictor is in the form of a tortuous serpentine-formed channel established between two members. In the latter the flow resistance is selectable just as a bolus function
10 is provided. Also US patent 5,993,414 discloses an infusion device utilizing a tortuous path flow restrictor.

In a second variant an infusion device comprises a first cavity containing a drive fluid, a flow restrictor comprising a flow channel, a second cavity in fluid communication with the first cavity through the flow channel, and a drug reservoir containing the drug to be infused, where
15 the second cavity and the drug reservoir is arranged such that the volume of the drug reservoir diminishes when the volume of the second cavity increases. Further, drive means for expelling the drive fluid from the first to the second cavity through the flow restrictor is provided, whereby drug is expelled from the drug reservoir. The force-transmitting interface between the second cavity and the drug reservoir could be described as a secondary pump actuated by the drive means. As appears, the drug flow rate will be determined by the applied force, the flow resistance in the flow restrictor and the viscosity of the drive fluid. Advantages
20 of the second variant are that the (delicate) drug does not have to be forced through the narrow flow restrictor and that a drive fluid having a high viscosity can be used thereby allowing a flow restrictor with a smaller flow resistance to be used which will normally be less expensive to manufacture. Examples of the second variant are disclosed in US patent 2,605,765 and German published patent application 25 52 446.
25

In the above referred infusion devices using the bleeding hole principle, it has been an object
30 to provide a constant infusion rate which has been achieved using force generating means providing a near-constant force, e.g. different forms of springs. However, it is also possible to use the bleeding hole principle in combination with flow rate controlling means as known from the infusion device described in EP 1 177 802, this infusion device comprising processor controlled valve means which opens and closes the drug flow generated using a bleeding
35 hole pump.

Although the bleeding hole principle thus has been proposed for a variety of drug infusion devices during the last five decades, it appears that the risks associated with this principle have until now not been properly identified. More specifically, the present inventors have realized that a pump based on the bleeding hole principle has a potential run-away risk if the flow restrictor is by-passed by alternative flow paths having a lower flow resistance, e.g. due to manufacturing errors or damage, which would result in the pump rate being too high which ultimately may result in drug overdosing.

A solution to this problem could be the provision of a flow sensor arranged close to the drug outlet and cooperating with alarm means, however, the provision of such additional systems would add considerably to the manufacturing costs, and be a major obstacle to the implementation of this pump principle for a prefilled, disposable infusion device.

DISCLOSURE OF THE INVENTION

Having regard to the above-identified problems, it is an object of the present invention to provide a flow restrictor suitable for use in a bleeding hole pump, which provides improved safety and can be manufactured in a cost-effective manner.

20

More specifically, the present invention is based on the realization that the risks associated with liquid bypassing the flow restrictor channel or portions thereof through alternative flow paths can be considerably reduced by properly designing the structures surrounding the flow restrictor channel. Flow restrictors may be provided by many different structures, however, flow restrictors in which (i) a flow channel is established between two cooperating portions of at least two members, and (ii) a flow channel is provided in the form of a capillary tube, appear especially suitable for use in medical delivery devices due to their simple construction and well defined properties.

When implementing the first principle, a given flow resistance may in principle be established by a narrow tubular channel of any desired length, however, a very short channel would have to be correspondingly narrow which would be difficult and expensive to manufacture. Therefore, a longer channel with a larger cross-sectional area is normally preferred, however, as this results in a relatively long channel it is necessary to "pack" the channel in an appropriate way, typically in a tortuous serpentine-like pattern comprising a plurality of U-formed portions

arranged close to each other, see for example EP 1 177 802 and WO 02/15965. As the flow channel is established between at least two members, it is essential that these two members are held properly in place against each other, e.g. by bonding. However, in case of manufacturing imperfections or subsequent damage the close contact between the members may be incomplete such that fluid would flow in the gap between two adjacent members and consequently be able to short-circuit portions of the tortuous path resulting in a (considerably) lower flow resistance.

Thus, in a first aspect the present invention provides a flow restrictor comprising a flow-restricting channel (in the following generally described as a "flow channel") formed between at least a first member and a second member arranged in contact with each other, the flow channel being arranged to form at least one generally U-formed portion with a pair of opposed first and second channel portions, and with a safety channel arranged between the opposed first and second channel portions, the safety channel providing a fluid communication with an exterior space relative to the flow restrictor. A flow restrictor of the invention may be formed integrally with the device in which it is implemented or it may be provided as a separate device or unit.

The safety channel establishes a flow path such that all or a portion of the fluid short-cutting the opposed channel portions in a given U-bend would be lead away from the flow channel, i.e. a "short-cut to the short-cut" is established. Preferably the safety channel is provided with a low flow resistance ensuring that substantially all fluid leaving the regular flow path is lead away, however, the exact flow resistance which will ensure this will be dependent upon both the characteristics and nature of the flow restrictor as well as the characteristics of other components of the drug delivery system. In this way drug infusion will stop and overdosing will be prevented. Indeed, in case underdosing is an issue, appropriate flow detection and alarm means may be provided.

In a preferred embodiment the flow channel as well as a plurality of safety channels is formed between two opposed surfaces. In such an arrangement a portion of a flow or safety channel is typically provided as an open trace or path formed in the surface of one member in combination with a planar portion of the other member which provides a "lid" thereby establishing a closed channel (indeed having one or two open ends). For a given flow restrictor the traces corresponding to different portions of the flow and safety channels may be provided in any of the two members in any desired configuration.

In a further preferred embodiment the flow channel as well as a plurality of safety channels is formed between an intermediate member sandwiched between two opposed surfaces. In such an arrangement through-going (i.e. perforating) traces are formed in the intermediate member, the through-going traces in combination with the opposed surface portions forming the flow channel and/or the safety channels. The intermediate member is preferably relative thin (e.g. a foil) in order to provide a narrow channel, correspondingly, the safety channels may be formed from traces in one or both of the opposed surfaces in combination with the foil. Although this arrangement results in the safety channels being arranged in a slightly different plane as the flow channel, for the purpose of the present disclosure they are considered to be arranged between the opposed portions of the individual U-portions.

As appears, numerous arrangements of the different channels or portions thereof can be contemplated just as channels formed from two, three or more members may be incorporated in a single flow restrictor.

When implementing the second principle, a fine capillary tube is used, the nature of which allows a relatively high flow resistance to be provided over a short length and at a low cost. As the capillary tube in most cases will be made from glass it is relatively fragile and it will be desirable to provide a supporting structure, however, in case a supporting structure (or any other structure) is provided surrounding the tube, a low resistance flow path may be established between the tube and the supporting structure, which in case of breakage of the fine tube may result in a dramatic reduction in flow resistance and a corresponding rise in the flow rate of the drive fluid.

Thus, in a second aspect the present invention provides a flow restrictor comprising a capillary tube having an outer surface and first and second end portions, a supporting structure supporting at least the first and second end portions, where the supporting structure is arranged such that a portion of the outer surface along substantially the entire length of the capillary tube is in fluid communication with an exterior space relative to the flow restrictor. In order to protect against breakage, the supporting structure preferably supports the capillary tube at one or more points along the length thereof between the first and second end portions. The supporting structure may be provided with inlet and outlet openings in communication with the respective ends of the capillary tube.

The supporting structure may comprise a safety channel in flow communication with the space surrounding the capillary tube, which channel may be in direct flow communication with the exterior space.

- 5 For both the first and second aspect of the invention, the exterior space relative to the flow restrictor may be represented by the "general space" surrounding an aggregate device in which the flow restrictor is incorporated or it may be an interior space in such a device. Indeed, in the latter case it should be prevented that any significant pressure builds up which would influence the function of the safety arrangement, e.g. by providing a relative large interior space or venting the interior space.
- 10

In a third aspect the present invention provides a delivery device comprising a first variable volume cavity containing a drive fluid, a flow restrictor as described above, a second variable volume cavity in fluid communication with the first variable volume cavity through the flow channel, a variable volume drug reservoir having in a situation of use an outlet, where the second variable volume cavity and the variable volume drug reservoir are arranged such that the volume of the drug reservoir diminishes when the volume of the second cavity increases. The delivery device further comprises drive means for expelling the drive fluid from the first to the second cavity through the flow restrictor such that drug is expelled from the drug reservoir through the outlet.

15

20

The outlet means may be adapted to be brought in fluid communication with infusion means (e.g. a catheter tubing or transcutaneous access means such as an infusion needle, a flexible infusion cannula or a plurality of micro-penetrators) or may comprise these. In the latter case the fluid communication may be established just prior to use, before or after the drug delivery device has been arranged on the user.

25

However, a delivery device of the above type may also be manufactured or offered to the user as a system in which individual components are combined with each other to provide an aggregate device. For example, it may be desirable to offer a system comprising a disposable, pre-filled drug unit, a durable drive-force providing unit and a disposable unit comprising the drive fluid and the flow restrictor. For such a system different flow restrictors providing different infusion rates in combination with a given drive-force could be offered.

30

Correspondingly, in a fourth aspect the present invention provides a fluid transmitting device comprising a first variable volume cavity containing a drive fluid, a flow restrictor as discussed and described above, a second variable volume cavity in fluid communication with the first variable volume cavity through the flow channel.

5

As used herein, the term "drug" is meant to encompass any drug-containing flowable medicine capable of being passed through a delivery means such as a hollow needle in a controlled manner, such as a liquid, solution, gel or fine suspension. Representative drugs include pharmaceuticals such as peptides, proteins, and hormones, biologically derived or active agents, hormonal and gene based agents, nutritional formulas and other substances in both solid (dispensed) or liquid form. In the description of the preferred embodiments reference will be made to the use of insulin. Correspondingly, the term "infusion" is meant to encompass any method of parenteral delivery to a subject.

10

15 **BRIEF DESCRIPTION OF THE DRAWINGS**

In the following the invention will be further described with references to the drawings, wherein

20 fig. 1A is an exploded perspective view of a flow restrictor device in accordance with the invention,

fig. 1B shows in part a cross-section of a further flow restrictor device,

25 fig. 1C shows in a cross-sectional side view a further flow restrictor device,

fig. 1D shows a cross-sectional view along the line D-D in fig. 1C,

fig. 2A shows a perspective view of an infusion device in an initial state,

30

fig. 2B shows a perspective view of the infusion device of fig. 2A in an actuated state,

fig. 3 shows a "horizontal" cross-sectional view of the infusion device of figs. 2,

35 fig. 4 shows a first "vertical" cross-sectional view of the infusion device of figs. 2,

fig. 5 shows a second "vertical" cross-sectional view of the infusion device of figs. 2,

fig. 6 shows in detail a flow restrictor, and

5

fig. 7 shows in detail a subcutaneous infusion needle.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

10 When in the following terms as "upper", "lower", "right" and "left" or similar relative expressions are used, these only refer to the appended figures and not to an actual situation of use. Further, the term "trace" is used to describe an "open" structure formed in a surface, e.g. a groove, whereas the term "channel" is used to describe a "closed" tubular structure which may have any cross-sectional configuration.

15

Fig. 1A shows a schematic representation of a first embodiment of the invention. Correspondingly, the configuration of the different structures as well as there relative dimensions are intended to serve illustrative purposes only.

20 More specifically, a flow restrictor device 101 comprises an upper member 110 with a generally planar lower surface 111 (cannot be seen in fig. 1A) and a lower member 120 with a generally planar upper surface 121. The upper member comprises first and second through-going bores 112, 113 serving as inlet respective outlet for the flow restrictor.

25 In the upper surface 121 is formed a flow trace 130 having an inlet end portion 131 and an outlet end portion 132 and a plurality of generally U-formed portions 135 each comprising a pair of opposed first and second "leg" portions 136, 137, the flow trace thereby forming a serpentine-like pattern. As appears, apart from the outermost legs, all the legs will form part of two neighbouring U-formed portions, i.e. legs 136, 137 will form a first U and legs 137, 138
30 will form a second U. The opposed portions may have any configuration (e.g. straight or curved) and may be arranged more or less in parallel with each other. For illustrative purposes is the trace 130 shown as a relatively broad structure, however, for most applications the trace will have a width and depth in the micrometer range.

In the upper surface 121 between each of the opposed portions 136, 137 of the flow trace is formed safety traces 140 having a closed end 141 arranged in the vicinity of the closed end of the U and an opposed open end 142 in communication with the exterior. As schematically illustrated in fig. 1 is the cross-sectional area of the safety traces substantially larger than the
5 flow trace.

In an assembled state (not shown) the two members 110, 120 are attached (e.g. bonded) to each other with the opposed surfaces in mating contact, whereby the flow trace and the safety traces will be "closed" to form a flow channel respectively a plurality of safety chan-
10 nels, the flow channel having an inlet end portion in fluid communication with the inlet opening 112 and an outlet end portion in fluid communication with the outlet opening 113.

As explained in detail above, should the bond between the two surfaces corresponding to a portion between two opposed legs 136, 137 of a U-formed portion 135 be defective, any fluid
15 shortcutting the trace will be drained to the exterior through safety channel 140.

Fig. 1B shows in part a schematic representation of a second embodiment of the invention. As in the first embodiment the flow restrictor device 201 comprises an upper member 210 with a lower surface 211 and a lower member 220 with an upper surface 221, however, in
20 the second embodiment an intermediate foil member 230 is sandwiched between the two opposed surfaces, the three members being bonded to form a laminate structure. In the foil member is formed a through-going (i.e. perforating) trace 239 having essentially the same configuration as the trace 130 in the first embodiment. In the lower surface of the upper member is formed a plurality of safety traces 240 having essentially the same configuration
25 as the safety traces 140 in the first embodiment. In this way a flow channel is formed between the three members in combination whereas the safety channels are formed between the first member and the intermediate member.

Figs. 1C and 1D show in schematic representation a third embodiment of the invention. The
30 flow restrictor device 301 comprises a capillary tube 330 mounted in a first support member 310. The first support member 310 has a first surface 311 comprising a groove 320 adapted to accommodate the capillary tube. The groove is slightly longer than the tube providing an inlet 321 and an outlet 322, and is configured to securely engage and support the tube at its end portions 331, 332. In addition, corresponding to a narrow portion along its length the
35 tube is supported on the lower surface 323 of the groove, just as two further supports 335

are provided however, corresponding to most of the surface of the tube, there is a clearance between tube and the support member. The first support member further comprises two safety traces 336, 337. In fig. 1D is the support member arranged against a second support member 340 whereby a support channel 320' is formed around the tube from which two safety channels 336' extend to the exterior. The second support member 340 comprises two bores 341 arranged in flow communication with the inlet respectively the outlet.

Fig. 2A shows a schematic representation of an embodiment of the invention. Correspondingly, the configuration of the different structures as well as there relative dimensions are intended to serve illustrative purposes only.

More specifically, fig. 2A shows an infusion device 1 comprising a housing 10 and therefrom protruding actuation button 20. The housing comprises an upper surface 2 and a lower surface 3 (not to be seen) adapted to be arranged against a skin surface of a user. The upper surface is provided with a transparent window 4 allowing the user to view a drug reservoir arranged within the housing. In fig. 2B the infusion device has been arranged against the skin of a user and the actuation button has pressed into the housing by the user thereby actuating the infusion device as will be explained in detail below.

With reference to figs. 3-5 the general construction of the infusion device will be described. The housing comprises an upper wall 11, a lower planar base plate 12, side wall portions, an end wall 13 with an outer planar surface, and relative to the latter an opposed open end. Internally the housing comprises a first central wall 14 and a second oblique wall 15 in combination defining three compartments, a drive compartment 16, a reservoir compartment 17 and a needle compartment 18. The drive compartment forms a flat cylinder with an open proximal end and a substantially closed distal end. A piston 30 is slidably arranged in the cylinder dividing the drive compartment in a distal fluid compartment 31 (corresponding to the above-described first cavity) filled with a viscous drive fluid (e.g. silicon oil), and a proximal spring compartment 32. The actuation button 20 comprises a skirt portion 21 slidably received in the cylinder thereby closing the spring compartment. In the spring compartment are arranged two helical compression springs 33 acting on the piston, however, any compressible material or member providing a spring action or any other means providing or generating a force (e.g. gas generating means or a liquid/gas mixture) acting on the piston may be utilized. The actuation button further comprises a wedge portion 22 to be received in the needle compartment.

As best seen in fig. 5 the reservoir compartment comprises a flexible drug reservoir 40 with an insulin-containing drug formulation. The reservoir is preferably manufactured from a transparent material allowing the user to view and control the drug through the window 4. In the initial state, i.e. before any drug has been expelled from the infusion device, the reservoir has a configuration substantially corresponding to the configuration of the reservoir compartment, thereby forming a neglectable cavity 19 (or dead-space) between the two components. In case an air filled dead space is not acceptable, the space may be filled with a fluid (for illustrative purposes is the gap between the reservoir and the reservoir compartment relatively large). As appears, the dead-space represents the above-described second cavity in a substantially fully collapsed state. Inside the drug reservoir is arranged a U-formed membrane element 41 formed from a self-sealing material and comprising upper and lower membrane portions 42, 43. In the end portion 13 is formed an outlet opening 34 from the fluid compartment and an inlet opening 44 to the reservoir compartment.

The infusion device further comprises a flow restrictor member 50 (see fig. 6) comprising a planer surface 51 in which a serpentine trace 52 is formed between proximal and distal end portions 53, 54. Between the opposed legs of the individual serpentine U-formed portions are arranged safety traces 59. The flow restrictor member 50 is bonded to the outer planar surface of the housing end portion with the proximal and distal end portions in register with the outlet 34 respectively the inlet openings 44. In this way a flow restrictor channel with safety channels is formed between the two openings. As appears, the resistance of the flow restrictor, the viscosity of the drive fluid and the force provided by the compressed springs will determine the rate at which the drive fluid will be forced through the flow restrictor to the reservoir compartment.

The infusion device further comprises a hollow subcutaneous infusion needle 60 as shown in fig. 7, comprising a distal pointed end 61 adapted to be introduced through a skin surface, a closed proximal end at which a needle wedge 62 is formed. In the body of the needle an opening 63 is formed in flow communication with interior of the needle. The proximal end of the needle is arranged in the needle compartment and with the needle body protruding through an opening 64 formed in the first wall 15 into the reservoir compartment and further into the reservoir. In the initial state (as supplied to the user and not shown in fig. 5) the needle penetrates the upper membrane portion 42 with the distal end 61 arranged between the upper and lower membrane portions 42, 43 inside the reservoir.

Next, with reference to figs. 4 and 5 actuation of the infusion device will be described. When the device has been positioned on a skin surface (preferably the lower surface comprises an adhesive coating) the user actuates the device by fully depressing the actuation button 20 until it locks in place in a recessed position (locking means arranged between the button and the housing is not shown in the figs.) whereby simultaneously the springs 33 are compressed and the wedge portion 22 is moved into the needle compartment. The wedge portion comprises a lower oblique surface 23 in sliding contact with the needle wedge 62 whereby the wedge portion forces the needle downwardly as it is pressed into housing. By this action the pointed distal needle end 61 penetrates the lower membrane portion 43 and is forced out through an opening 65 formed in the base portion. As the infusion device is attached to the skin surface of the user, the infusion needle is hereby introduced through the skin. When the needle is in its fully extended position, the needle opening 63 is positioned between the two membrane portions whereby a fluid communication is established from the drug reservoir to the user. At the same time the drive fluid starts to be expelled from the fluid compartment 31 and through the flow restrictor to the cavity portion 19 of the reservoir compartment 17 where it gradually will compress the flexible reservoir and thereby force out the therein contained insulin-containing drug through the needle and into the user.

Initially air will be expelled from the needle just as air trapped in the flow restrictor and around the drug reservoir (if any) may result in an initial higher infusion rate, however, these effects will be neglectable.

In the shown embodiment the expelling means in form of springs 33 are "energized" during actuation of the device, however, to reduce the force needed to actuate the button 20 the spring means 33 may be pre-tensioned and the drive fluid 31 correspondingly pre-pressurized, whereby alone puncturing of the reservoir by the needle will actuate the expelling means and thereby start infusion.

In the above description of the preferred embodiments, the different structures providing the desired relations between the different components just as the means providing the described functionality for the different components (i.e. force generating means, flow restrictor, flexible reservoir etc.) have been described to a degree to which the concept of the present invention will be apparent to the skilled reader. The detailed construction and specification for

the different structures are considered the object of a normal design procedure performed by the skilled person along the lines set out in the present specification.

Claims

1. A flow restrictor (101) comprising:

- a flow channel (130) formed between at least a first member (110) and a second member (120) arranged in engagement with each other,
- the flow channel having an inlet end portion (131) in fluid communication with an inlet (112) opening and an outlet end portion (132) in fluid communication with an outlet opening (113),
- the flow channel comprising a generally U-formed portion (135) with a pair of opposed first and second channel portions (136, 137), and
- a safety channel (140) arranged between the opposed first and second channel portions,
- the safety channel comprising an end portion (142) in fluid communication with an exterior space relative to the flow restrictor.

2. A flow restrictor as defined in claim 1, comprising a plurality of generally U-formed portions, each with a pair of opposed first and second channel portions.

3. A flow restrictor as defined in claim 2, comprising a plurality of safety channels arranged between at least a portion of the opposed first and second channel portions.

4. A flow restrictor as defined in any of claims 1-3, wherein:

- the first member comprises a first surface portion (111) and the second member comprises a second surface portion (121), the first and second surface portions being arranged in opposed engagement with each other, and wherein
- traces (130, 140) are formed in at least one of the first and second surface portions, the traces in combination with an opposed surface portion forming the flow channel and the safety channel(s).

5. A flow restrictor as defined in claim 4, wherein the surface traces are formed in one of the first and second surface portions.

6. A flow restrictor as defined in any of claims 1-3, wherein:

- the first member (210) comprises a first surface portion (211) and the second member (220) comprises a second surface portion (221), the flow restrictor further comprising an

intermediate member (230) arranged between the first and second surface portions and in engagement therewith, and wherein

- at least one through-going trace is (239) formed in the intermediate member, the through-going trace(s) in combination with opposed surface portions forming at least a portion of the flow channel and/or the safety channel(s).

7. A flow restrictor as defined in claim 6, wherein traces (240) are formed in at least one of the first and second surface portions (211, 221), the traces in combination with opposed portions of the intermediate member forming at least a portion of the flow channel and/or the safety channel(s).

8. A flow restrictor as defined in any of the previous claims, wherein the inlet and outlet openings (112, 113) are formed in the first and/or second member.

15

9. A flow restrictor (301) comprising:

- a capillary tube (330) having first and second opposed end portions (331, 332) and an outer surface,
- a supporting structure (310, 340) supporting the first and second end portions,
- the supporting structure being arranged such that a portion of the outer surface along substantially the entire length of the capillary tube is in fluid communication with an exterior space relative to the flow restrictor.

10. A flow restrictor as defined in claim 9, wherein the supporting structure supports the capillary tube at least at one point (335) between the first and second end portions.

11. A flow restrictor as defined in claim 9 or 10, wherein the supporting structure comprises inlet and outlet openings (341) in communication with the respective ends of the capillary tube.

30

12. A delivery device (1) comprising:

- a first variable volume cavity (31) containing a drive fluid,
- a flow restrictor (50, 52) as defined in any of the previous claims,
- a second variable volume cavity (19) in fluid communication with the first variable volume cavity through the flow channel,

35

- a variable volume drug reservoir (40) having in a situation of use an outlet means,
- the second variable volume cavity and the variable volume drug reservoir being arranged such that the volume of the drug reservoir diminishes when the volume of the second cavity increases, and

5 - drive means (33) for expelling the drive fluid from the first to the second cavity through the flow restrictor, whereby drug is expelled from the drug reservoir through the outlet.

13. A fluid transmitting device comprising:

- 10 -
- a first variable volume cavity containing a drive fluid,
 - a flow restrictor as defined in any of the previous claims,
 - a second variable volume cavity in fluid communication with the first variable volume cavity through the flow channel.

Abstract

The present invention relates to a flow restrictor suitable for the controlled transfer of fluid from a first compartment to a second compartment. More specifically, the invention relates to a safety arrangement reducing the risks associated with diminished flow resistance through the flow restrictor. In a first aspect the present invention provides a flow restrictor comprising a flow-restricting channel formed between at least a first member and a second member arranged in contact with each other, the flow channel being arranged to form at least one generally U-formed portion with a pair of opposed first and second channel portions, and with a safety channel arranged between the opposed first and second channel portions. The safety channel provides a fluid communication with an exterior space relative to the flow restrictor. A flow restrictor of the invention may be formed integrally with the device in which it is implemented or it may be provided as a separate device or unit.

15

20

25

Fig. 1A

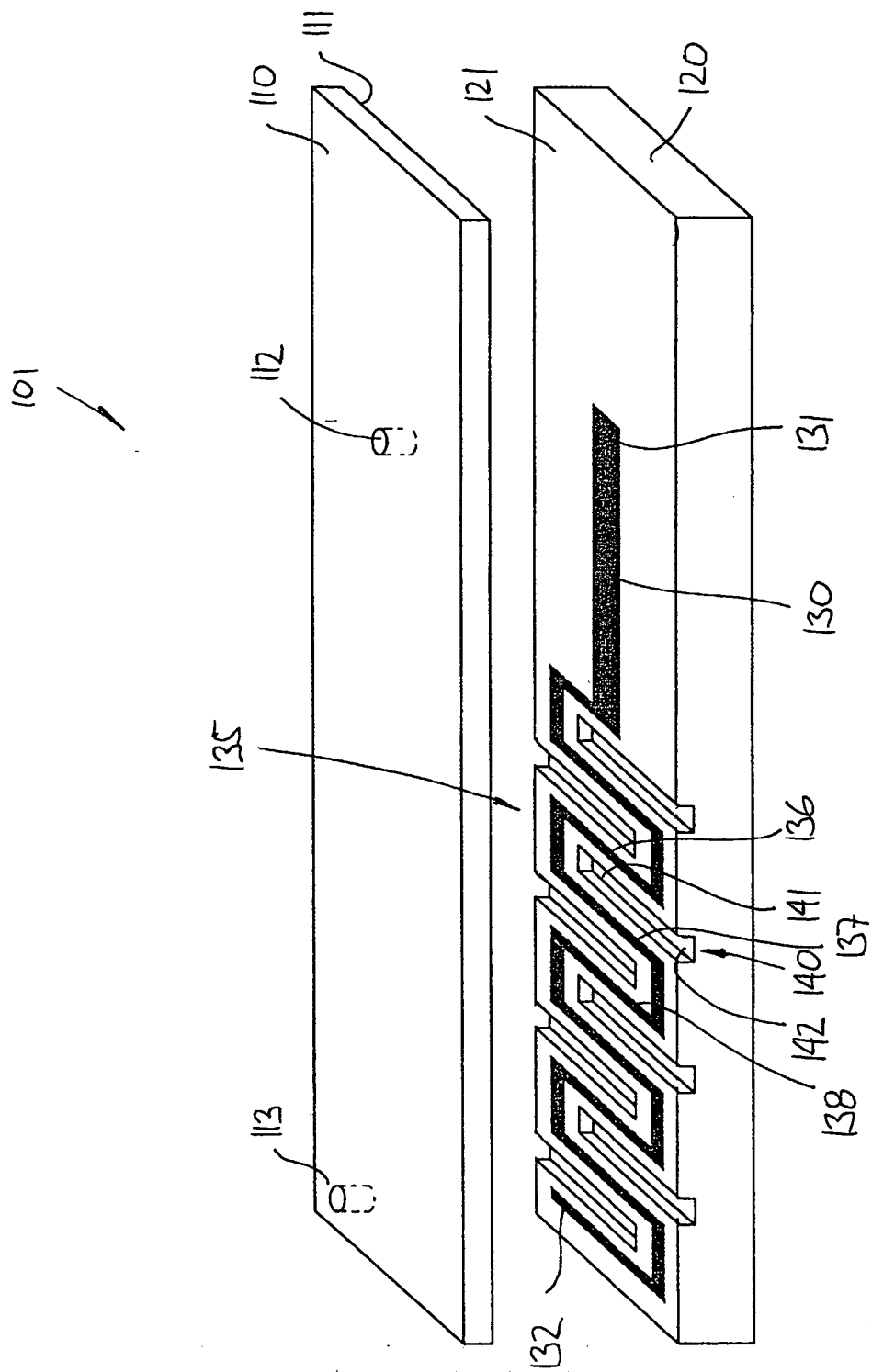


Fig. 1B

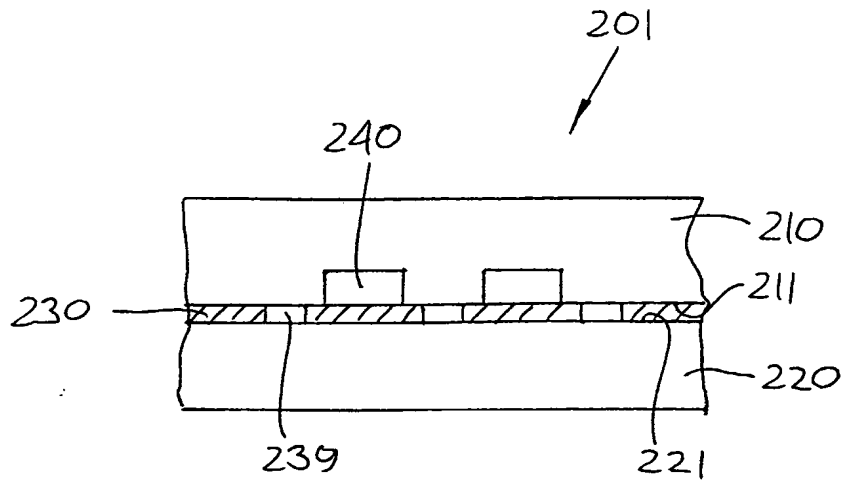


Fig. 1C

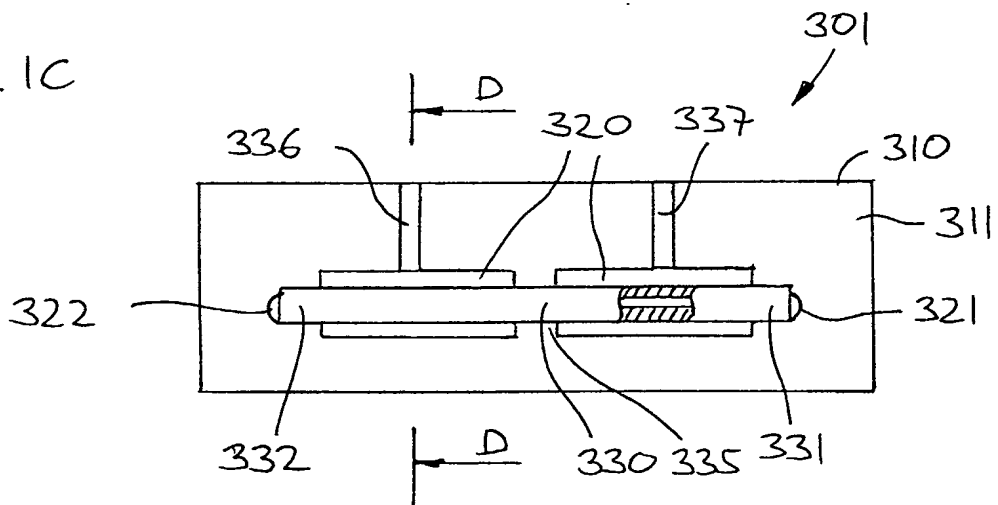


Fig. 1D

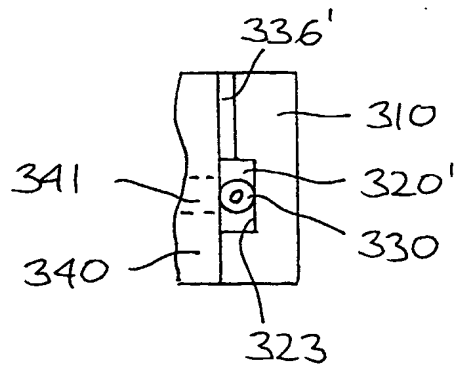


Fig. 2A

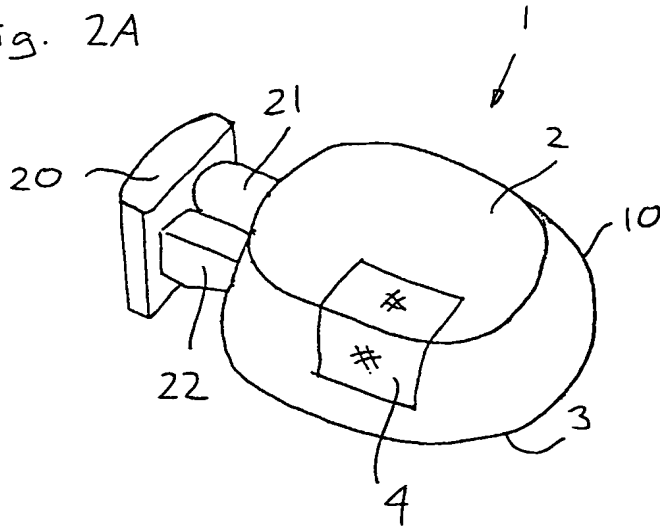


Fig. 2B

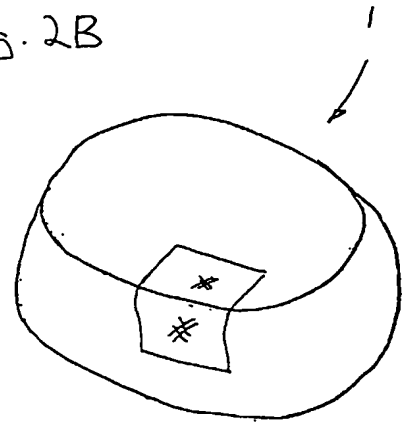


Fig. 3

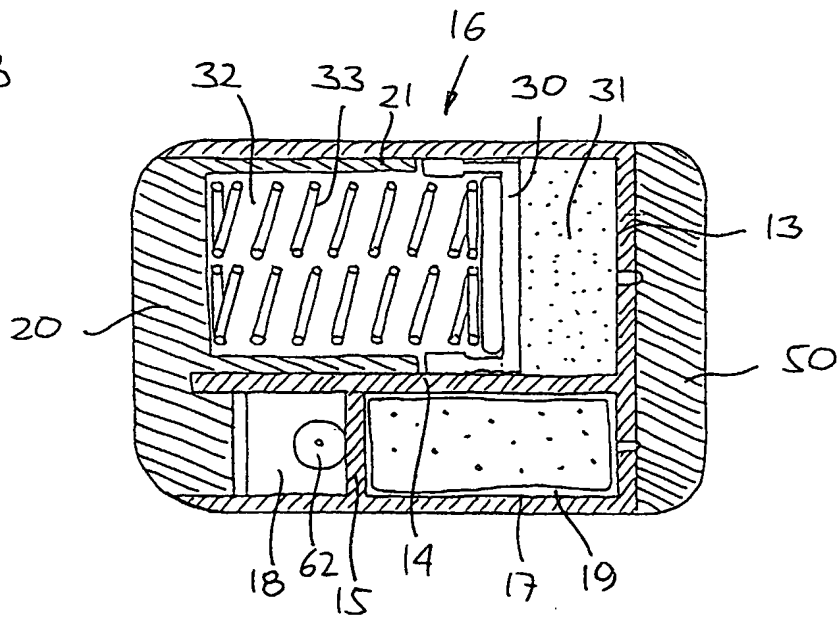


Fig. 4

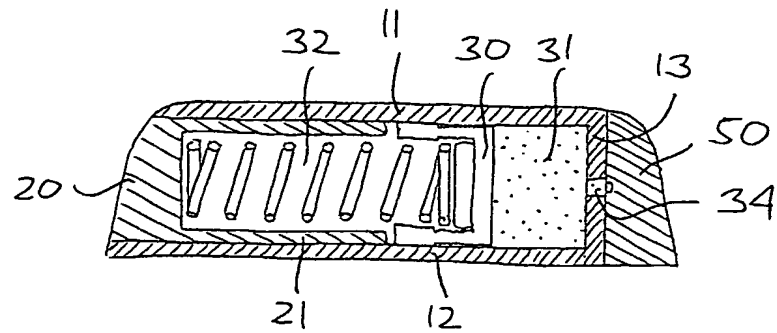


Fig. 5

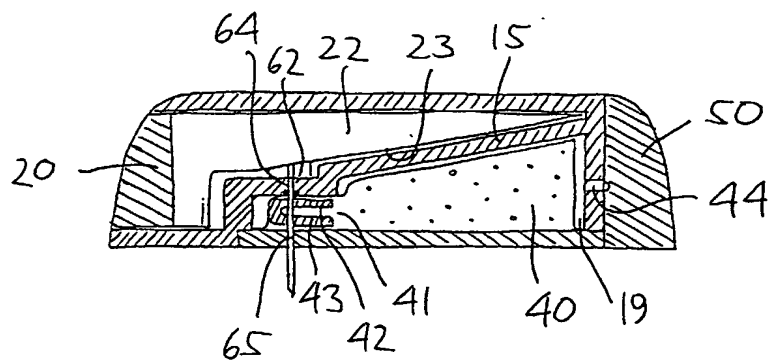


Fig. 6

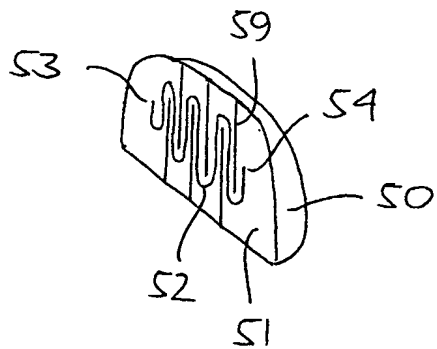


Fig. 7

